

November 27, 2002

Office of Public Health and Science & FDA, HHS  
Dockets Management Branch (HFA-305)  
Docket Number 02N-0466  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061, Rockville, MD 20852

RE: Solicitation of Public Review  
and Comment of Research Protocol:  
A Multicenter, Randomized Dose Response  
Study of the Safety, Clinical and immune  
Response of Dryvax Administered to  
Children 2 to 5 years of age  
Docket No. 02N-0466

To Whom It May Concern:

Throughout the past month I have been reading a lot about the study dealing with the administration of the smallpox vaccine to 40 children from the ages 2 to 5. There are many conflicts within the study that I believe need to be taken into consideration. This study should not take place for many reasons, particularly due to the safety of the children.

When I heard that the study was going to be administered on children of such a young age I was shocked, especially after learning the details. The vaccine being used is made of a live virus that is called vaccinia, which alone has its own risks. The vaccinia can cause infections of its own if it comes in contact with something before the place that was injected scabs over. The researchers that are involved with the study expect to keep these children inoculated for one month. This month is very important when it comes to the mental and social development of the children.

The children are in danger if administered this vaccine because children of that age are rebellious. If the children are told not to touch the bandage they are immediately going to try and take it off which can cause serious long-term effects. If the children remove their bandages and come in contact with another person they can infect that person with the smallpox virus. This puts everyone around the child in danger of the possibility of getting this virus. The children can also harm themselves because if they touch the injected area and then come in contact with their eyes it can cause blindness, or if the mouth is touched they can catch the virus itself.

Fifteen out of every one million people have life threatening reactions and one or two of them will die from the vaccine. The Bush Administration wants to give this vaccine to 280 million Americans. That means that 4,200 people will have life-threatening reactions and between 280 and 560 people will die. All this will take place

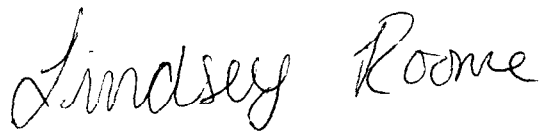
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because of a virus that has not been around since the 1960's. The only way there will be a smallpox outbreak is if there is a bioterrorist attack with the virus. Is it worth it to put these 40 children in danger for something that we aren't even sure about? Do we know the probability of a bioterrorist attack occurring with the smallpox virus? The most unethical part of this study is that the children may not even be benefiting from it.

If this test is administered, what kinds of children are going to be picked? Is there going to be money involved so that the poor flock to volunteer their children? If this vaccine is administered who is going to be accountable for the people that may become infected with the virus? There are many questions that have been left unanswered that play a big role in the administration of the vaccine. "I would certainly want these trials to be conducted before I would want my child to be vaccinated," said Dr. Julia McMillan of Johns Hopkins University, a spokeswoman for the American Academy of Pediatrics. I believe most parents would also feel this way, so before any further testing, I myself along with the rest of the public deserve to know the major details.

Sincerely Yours,

A handwritten signature in cursive script that reads "Lindsey Roome". The signature is written in dark ink and is positioned above the printed name.

Lindsey Roome